Dot Compliance

From Paper to Digital Platform: How Shorla Oncology Evolved Its Quality Operations

Challenge

As a growing pharmaceutical company, Shorla Oncology (Shorla) needed a structured and scalable way to manage quality documentation, training, and compliance while maintaining full regulatory control. Prior to implementing Dot Compliance, the organization relied heavily on paper-based processes supported by a mix of cloud-based storage and electronic signature platforms.

This approach made tracking documents, maintaining version control, and preparing for audits increasingly complex. Quality information was distributed across physical files and digital repositories, which limited visibility and created inefficiencies as the organization expanded.

"As we all know, the paper-based approach is very difficult in regards to tracking," Breda Gahan, Shorla's quality and compliance manager shared.

Shorla recognized that continuing with paper-based systems would not support long-term compliance or operational efficiency. The company needed an electronic Quality Management System (eQMS) that could centralize documentation, preserve historical accuracy, and support compliance throughout the transition without disrupting day-to-day operations.

Solution

Shorla selected Dot Compliance as its eQMS to bring quality documentation, training, and core QMS processes into a single, centralized platform.

A key priority during implementation was maintaining compliance while transitioning from paper-based workflows. Rather than deploying all modules at once, Shorla took a phased, module-by-module approach, beginning with document management and training before expanding into change control, deviations, and additional quality processes.

"We took it each module at a time," Gahan explained, "understanding and maintaining compliance during the transition for all modules."

Dot Compliance's ability to migrate documents at their existing revision levels was especially important. This allowed Shorla to preserve document history and continuity without restarting version control from scratch.

Gahan said, "I was very impressed with that point of view, where we could have the documents logged in and put into the system at their current revision...we didn't have to start at zero."

Shorla deployed Dot Compliance largely out of the box, leveraging preconfigured workflows while aligning the system to internal processes as needed.

About

Shorla Oncology is a privately held, U.S. and Ireland- based commercial-stage specialty pharmaceutical company established by Sharon Cunningham and Orlaith Ryan. The company has an advanced pipeline of innovative oncology drugs for orphan and pediatric cancers. Shorla is focused on indications where existing treatments are limited, in short supply, or the drug applications are inadequate for the target population. The company's growing portfolio brings accessible, affordable, and life-saving treatments to patients, delivering a major contribution to patient care. Shorla currently markets four products: Nelarabine for the treatment of T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) in adult and pediatric patients whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens, JYLAMVO®for the treatment of acute lymphoblastic leukemia and other indications, IMKELDI® for the treatment of Chronic Myeloid Leukemia, Gastrointestinal Stromal Tumors (GISTs), and other indications, and TEPULYTE® for the treatment of breast and ovarian cancer. For further information, please visit **www.shorlaoncology.com.**

SHORLA ONCOLOGY
THE HEART OF INNOVATION

Industry   Pharmaceuticals

Location   Ireland

Ongoing support also played a critical role in long-term adoption. Gahan emphasized the importance of having a knowledgeable Customer Success Manager (CSM) to provide guidance, answer questions, and help navigate updates and enhancements as usage expanded.

She said, "It's critical to have a very strong, knowledgeable CSM to answer any questions, to sort out any issues we may have or to get over some obstacles."

Benefits

Dot Compliance delivered immediate improvements in visibility, efficiency, and audit readiness across Shorla's quality operations. Centralizing documents and training records enabled teams to quickly locate controlled information, maintain confidence in document accuracy, and respond more efficiently during audits.

Gahan shared, "The ability the system gives us to put in the historical information from our paper documents into the system has saved a lot of time."

Reporting capabilities further reduced manual effort. Shorla was able to configure reports that automatically update as new records are added, eliminating the need to compile information across multiple sources.The team was able to go into the system, set up the report and have it completed in minutes.

Search functionality and centralized access have improved day-to-day efficiency while supporting inspection readiness.

Beyond documentation, Dot Compliance has improved collaboration across the organization by providing consistent workflows and a user-friendly interface that encourages adoption. As more departments began using the system, confidence and engagement increased.

Shorla has continued expanding usage into additional areas, including binders, supplier oversight, and cross-functional reporting, allowing the platform to support both current operations and future growth.

Looking Ahead

Shorla continues to evolve its use of Dot Compliance as part of its long-term quality strategy.

According to Gahan, "We're always constantly looking to see what else is in Dot Compliance and how we can get as much as we can from it."

For Shorla, Dot Compliance provides a scalable foundation that supports compliance today while offering flexibility to adapt as regulatory expectations and business needs evolve.

"I would definitely highly recommend Dot Compliance. I'm very impressed with the different functionalities that I have not seen in other quality systems before. In the audit module, I'm particularly impressed by how streamlined and easy it is to write up an internal audit, and then generate the audit report. These things make life much easier. The system drives you to lean out your processes, think outside the box and remove steps you didn't need before."

Breda Gahan,
Quality and Compliance Manager